K014/12

510(k) Summary

As Required by 21 section 807.92 (c)

FEB 2 8 2002

1-Submitter Name: Siam Sempermed Corp., Ltd
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5-Contact Person: Dr Poonsuk Cherdkiatgumchai (Chief Quality Officer)
6-Date summary prepared: December 7th, 2001
7- Official Correspondent: Mansour Consulting
8- Address: 1308 Morningside Park Dr Alpharetta, GA 30022 USA
9- Phone: (678) 908-8180
10- Fax: (425) 795-9341
11- Contact person: Jay Mansour, president
12-Device Trade or Proprietary Name: SATARI® latex patient examination powdered glove single side polymer coated, non sterile, 200 µg or less of total water extractable protein per gram, 10 mg/dm^2 or less of residual powder
13-Device Common or usual name: Examination glove
14-Device Classification Name: Glove, Patient Examination, Latex
15-Substantial Equivalency is claimed against the following device:
Siam Sempermed Latex Patient Examination Glove Polymer powder free, 510k #k981096 (refer to Appendix 2 for FDA website printout. This notification for the SATARI® latex examination glove is of the ABBREVIATED type as per the declaration of conformity on page 4 of this summary

11-Description of the Device:
SATARI® latex patient examination glove, is a powder glove single side polymer coated, non sterile, 200 µg or less of total water extractable protein per gram, 10 mg/dm^2 or less of residual powder

12-Intended use of the device: *(Indications for use typed on a separate FDA form)*
This device is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner

13-Safety and effectiveness of the device:

This device is safe and effective as the predicate device ***Siam Sempermed Latex Patient Examination Glove polymer,*** *powder-free.* Indeed, it is equivalent.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

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General comparison result between **SATARI® latex examination glove** and the predicate device (***Siam Sempermed Latex Patient Examination Glove polymer,*** *powder-free*) is tabulated below.

Technical comparison of specific elements is attached in the main submission

FDA file reference number	510k 970794
Attachments inside notification submission file	REFER TO APPENDIX 2
TECHNOLOGICAL CHARACTERISTICS	*Comparison result* **REFER TO ADDITIONAL TECHNICAL COMPARATIVE TABLE WITHIN 510K SUBMISSION**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Identical
Performance	Identical
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical (not applicable)
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2002

Siam Sempermed Corporation Limited
C/O Mr. Jay Mansour
Mansour Consulting
1308 Morningside Park Drive
Alpharetta, Georgia 30022

Re: K014112
Trade/Device Name: Satari Powdered Latex Examination Gloves with Protein Content Labeling Claim (200 Micrograms or Less) Polymer Coated White, Pink and Blue
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: December 10, 2001
Received: December 14, 2001

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014112

Device Name: SATARI® LATEX PATIENT EXAMINATION POWDERED GLOVE, SINGLE SIDE POLYMER COATED, NON STERILE 200µg OR LESS OF TOTAL WATER EXTRACTABLE PROTEIN PER GRAM, 10 mg/dm² OR LESS OF RESIDUAL POWDER

Indications For Use: (White, Pink, and Blue)

THIS DEVICE IS A DISPOSABLE DEVICE INTENDED FOR MEDICAL PURPOSES THAT IS WORN ON THE EXAMINER'S HAND TO PREVENT CONTAMINATION BETWEEN PATIENT AND EXAMINER

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chris S. Lin

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K014112

Prescription Use _____ (Per 21 CFR 801.109) OR Over-The-Counter Use X

(Optional Format 1-2-96)